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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,210	10/16/2001	Shian-Jiun Shih	A2922AUS	2753
5487 7590 05/17/2007 ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER EPPS FORD, JANET L	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 05/17/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com  
andrea.ryan@sanofi-aventis.com

## Office Action Summary

**Application No.**

09/763,210

**Applicant(s)**

SHIH ET AL.

**Examiner**

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-5, 7-13, 18, 22-24, 26, 27 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5, 7-13, 18, 22-24, 26, 27 and 34-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 3-5, 7-13, 18, 22-24, 26, 27 and 34-39 are presently pending for examination.

### ***Response to Amendment***

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3-5, 7-13, 18, 22-24, 26, 27 and 34-39 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter).

5. Applicant's arguments filed 2-28-07 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the various passages of the specification, listed on page 7 of Applicant's response filed 2-28-07, "all indicate that applicants envisioned their invention to encompass temperatures above 4°C. In addition, Example 6 provides data for the temperatures of 4°C and 20°C. The presence of data for these two temperatures would put the skilled artisan on notice that

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applicants were in possession of not only these two points but also all those points in between. The skilled artisan would not expect the results of experiments performed at the temperatures of 5°C, 6°C... 18°C and 19°C, etc. to differ significantly from applicants' results for the temperatures of 4°C and 20°C. The disclosures and data of the present application taken together with the knowledge of the skilled artisan, clearly indicate that applicants were in possession of the claimed range. “ Contrary to Applicant's assertions, the passages of the specification as filed cited by Applicant's support for the temperature range “from about 4°C to about 20°C,” provide only support for temperatures greater than 4°C. The phrase “about 4°C” is not limited to wherein the temperatures are greater than 4°C, the scope of this phrase also includes temperatures that are below 4°C. Therefore, although the examiner agrees with Applicant's position that the specification provides support for temperatures greater than 4°C, there is no support for any temperature below 4°C. Applicants must cancel the new matter in response to this Office Action.

Moreover, Applicants have amended claims 3-5, 7-13, 18, 22-24, 26-27, and 34-39 were amended to recite a composition consisting of human serum albumin (HSA), wherein the concentration of HSA is from about 0.01% to about 25% (w/v). However, the specification as filed does not provide support for this amendment. The specification describes a composition comprising human serum albumin, wherein the concentration of HSA is from about 0.01% to about 25% (w/v), it is clear that in order to make a composition comprising from about 0.01% to about 25% (w/v) other components are present in the composition, otherwise if the composition consists of

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HSA, the concentration of the HSA in the composition would be 100%. Therefore the limitations regarding the concentration of HSA in the claimed compositions are improper and unsupported since they are suggestive of the presence of another component.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-5, 7-13, 18, 22-24, 26, 27 and 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended the instant claims to recite a composition consisting of "human serum albumin (HSA), wherein the concentration of HSA is from about 0.01% to about 25% (w/v)..." This phrase is vague and indefinite since it is clear that in order to make a composition comprising from about 0.01% to about 25% (w/v) other components are present in the composition, otherwise if the composition consists of HSA, the concentration of the HSA in the composition would be 100%. Therefore, applicant's amendment to the claims by replacing the term "consisting essentially of" with "consisting of" is ambiguous, since it is clear that the specification as filed does not contemplate compositions comprising 100% HSA.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 103***

8. The rejection of claims 7-13, 22-24, 26, and 34-39 under 35 U.S.C. § 103(a) as being unpatentable over Crespo in view of Engler et al. (US 2003/021 1598); and claims 3-5, 7-13, 18, 22-24, and 26-27, 34-38 under 35 USC 103(a) as being unpatentable

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over Crespo in view of Engler et al. (US 2003/021 1598), and further in view of Rolland et al. and Sene, are withdrawn in response to Applicant's amendment.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

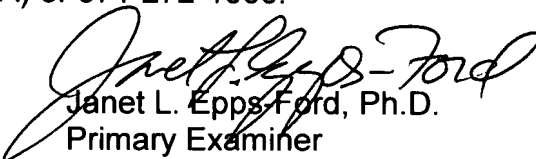
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Janet L. Epps-Ford, Ph.D.  
Primary Examiner  
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JLE